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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,344	01/31/2001	John T. McDevitt	5119-00525	7208

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ERIC B. MEYERTONS  
 CONLEY, ROSE & TAYON, P.C.  
 P.O. BOX 398  
 AUSTIN, TX 78767-0398

EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/775,344	MCDEVITT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leon Y Lum	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 309,347-395,428 and 440-459 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 309, 347-395, 428, 440-459 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claim 309, drawn to a system for detecting an analyte in a bodily fluid, classified in class 422, subclass 82.05.
- II. Claims 347-394, drawn to a method of sensing an analyte in a bodily fluid, classified in class 435, subclass 5.
- III. Claim 395, drawn to a system for detecting a nucleic acid analyte in a fluid, classified in class 422, subclass 82.05.
- IV. Claim 428, drawn to a sensor array for detecting a nucleic acid analyte in a fluid, classified in class 422, subclass 68.1.
- V. Claims 440-459, drawn to a method of sensing a nucleic acid analyte in a fluid, classified in class 435, subclass 6.

2. Inventions I and II are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a filtration process.

3. This relationship is also applicable to Inventions I and V.

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4. Inventions I and III are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions. Group I claims a system that includes a particle that comprises a receptor molecule coupled to a polymeric resin, which would produce analyte interactions different from Group III, which lacks the receptor molecule and polymeric resin. Group III is also specific for nucleic acid detection, whereas Group I is not limited to one type of analyte.

5. Inventions I and IV, are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system of Group I does not require the specific sensor array of Group IV for patentability. The sensor array of Group I includes receptor molecules on particles and a supporting member that allows for one or more cavities, and is different from the sensor array of Group IV, which is specific for a plurality of cavities and does not include receptor molecules on the particles. The subcombination has separate utility such as a pH sensor.

6. Inventions II and III are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as the filtration of analytes.

7. This relationship is also applicable to Inventions II and IV.

8. Inventions II and V are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions. Group II claims a method that includes particles comprising a receptor coupled to a polymeric resin, which would produce analyte interactions different from Group V, which lacks the receptor and would interact with different types of analytes. Group II is also specific for nucleic acid analytes whereas Group V is not limited to one type of analyte.

9. Inventions III and IV, are related as combination and subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the

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combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system of Group III does not require the specific sensor array of Group IV for patentability. The sensor array of Group III includes receptor molecules on particles and a supporting member that allows for one or more cavities, and is different from the sensor array of Group IV, which is specific for a plurality of cavities and does not include receptor molecules on the particles. The subcombination has separate utility such as a pH sensor.

10. Inventions III and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as a process of filtration.

11. This relationship is also applicable to Inventions IV and V.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different

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classification, and the search required for each of Inventions I-V are not required for the others, restriction for examination purposes as indicated is proper.

13. In the event that applicant elects Group II the following species election must also be made:

Species 1: one analyte and,

Species 2: one spectroscopic change and,

Species 3: one signal

Species 1: analyte in bodily fluid

- a. bacteria, claims 348-349,351
- b. parasite, claims 353-355
- c. virus, claims 356-357
- d. carbohydrate, claim 361
- e. steroid, claim 362
- f. triglyceride, claim 363
- g. homocysteine, claim 364
- h. anticonvulsive drug, claim 365
- i. opiate, claim 369
- j. cocaine, claim 370
- k. marijuana, claim 371
- l. electrolyte, claim 372

In the event that applicant elects Species 1a the following species election must further be made:

- i. mastitis bacteria, claim 350
- ii. mycobacterium tuberculosis, claim 352

In the event that applicant elects Species 1c the following species election must further be made:

- i. feline leukemia virus, claim 358
- ii. HIV virus, claim 359
- iii. Hepatitis C virus, claim 360
- iv. Feline leukemia, claim 373

In the event that applicant elects Species 1h the following species election must further be made:

- i. amphetamine, claim 366
- ii. barbiturate, claim 367
- iii. benzodiazepine, claim 368

Species 2: spectroscopic change

- a. absorbance, claim 374
- b. fluorescence, claim 375
- c. phosphorescence, claim 376



Species 3: signal produced

- a. absorbance, claim 393
- b. fluorescence, claim 394

14. Currently, claims 347, 377-392 are generic. Claims 348-376 and 393-394 are subject to species election.

15. For example, the election comprises Group II and Species 1a(i), claim 350; and Species 2a, claim 374; and Species 3b, claim 394. Thus claims 347-351, 374, 377-392, and 394 comprise the elected invention.

16. In the event that applicant elects Group V the following species election must also be made:

- Species 1: one signal and,
- Species 2: one receptor and,
- Species 3: one analyte and,
- Species 4: one amplification method and,
- Species 5: one intercalator

Species 1: signal

- a. absorbance, claim 441

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- b. fluorescence, claim 442

Species 2: receptor

- a. RNA, claims 443-444, 446
- b. DNA, claims 445, 447, 450
- c. protein, claims 448-449

Species 3: analyte in bodily fluid

- a. DNA, claims 443, 445, 447-448, 450
- b. RNA, claims 444, 446, 449

Species 4: amplification method

- a. polymerase chain reaction, claim 451
- b. ligase chain reaction, claim 452

Species 5: intercalator in second fluid

- a. hydroxylamine, claim 456
- b. potassium permanganate, claim 456
- c. tetraethyl ammonium acetate, claim 456
- d. osmium tetroxide, claim 456
- e. ethidium bromide, claim 456
- f. POTO, claim 456
- g. Texas Red, claim 456

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17. Currently, claims 440, 453-455, and 457-459 are generic. Claims 441-452, and 456 are subject to species election.

18. For example, the election comprises Group V and Species 1b, claim 442; and Species 2b, claims 445, 447, and 450; and Species 3a, claims 443, 445, 447-448, 450; Species 4a, claim 451; and Species 5e, claim 456. Thus claims 440, 442, 445, 447, 450-451, and 453-459 comprise the elected invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

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must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

04/05/04